

**Technology and Equipment
Committee Meeting**

August 29, 2007

CARDIAC CATHETERIZATION MATERIAL

Material Related to

Petition-2: Scotland Memorial



August 1, 2007

From: Gregory C. Wood, President and CEO
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DFS Health Planning
RECEIVED

AUG 02 2007

Medical Facilities
Planning Section

To: State Health Coordinating Council, and
Medical Facilities Planning Section
Division of Facility Services
2714 Mail Service Center
Raleigh, North Carolina 27699-2714

Re: **PETITION:** Scotland Memorial Hospital; Requests adjustment in the Shared Fixed Cardiac Catheterization Equipment Need Determination for Scotland County as set forth on page 153 in the *Proposed 2008 State Medical Facilities Plan (SMFP)* to identify a need for one unit of shared fixed cardiac catheterization equipment in Scotland County.

Petition

By this petition, Scotland Memorial Hospital (SMH) requests that the Medical Facilities Planning Section adjust the *Proposed 2008 SMFP* to show a specific need for one unit of shared fixed cardiac catheterization equipment in Scotland County. Table 9Y on Page 153 would reflect these changes:

Hospital Service System	Shared Fixed Cardiac Catheterization Equipment Need Determination	Certificate of Need Application Due Date	Certificate of Need Beginning Review Date
Scotland	1	April 15, 2008	May 1, 2008

Scotland Memorial reported performing 427 mobile cardiac catheterizations in 2006.¹ This number is just 20 procedures shy of reaching the threshold to justify a unit.

Hours per Day	Days per Week	Total Hours per Week	per "8-hour Day" per Week	SMH Threshold	SMH 2007 HLRA Reported	Threshold # Variance	Threshold % Variance
7.45	2	14.90	240	447	427	20	4.7%

The methodology works against success in reaching the required threshold. As volume builds, scheduling demands push administration to add more time on the mobile unit. With each added day, the methodology sets a higher threshold, keeping success just outside the host site's reach. Scotland Memorial Hospital, in fact, surpassed the 240 procedure threshold for one day in 2003 and was forced to add another day to provide its service area patients with adequate access to quality cardiac care. Once again, Scotland Memorial is close to the threshold and offering good access to patients suggests adding a day, but if another day of mobile service is added, the threshold will be pushed further out of reach.

As part of its community mission, Scotland Memorial Hospital must strive to develop its cardiac care program. Its service area patients need and deserve a more fully developed cardiac care program close to home.

Cardiac catheterization is a key element in a cardiac care program because it is the definitive tool for diagnosis and management of coronary artery disease. Cardiac catheterization is among the top five hospital procedures performed on males, according to the Agency for Healthcare Research and Quality. The cardiac catheterization rate for all hospitalized patients nationwide was 6.2 per 1000.² Increasingly, cardiac catheterization is an outpatient procedure, and those procedures are not reflected in the numbers above.

The advent of 64-slice computed tomography made it possible to capture images of coronary arteries non-invasively (CTA). CTA is a diagnostic alternative primarily valuable for ruling out coronary artery blockage as a cause of cardiac problems.³ Cardiac CT has the potential to become a complementary tool to invasive coronary catheterization.⁴ However, a technology assessment, TA 6.57 Computed Tomography Angiography (CTA) for Coronary Artery Disease, performed in October 2006 by Harvard Pilgrim HealthCare resulted in the following policy: "Computed Tomography Angiography (CTA) for coronary artery disease is a new and promising technology, but remains investigational, unproven, and experimental. HPHC will cover on a case by case

¹ 2007 Hospital License Renewal Application

² Advance Data from Vital and Health Statistics No. 385, July 12, 2007, Center for Disease Control

³ Health Imaging and IT, July 2007, pg 40

⁴ <http://www.cathlabdigest.com/article/962>, Research Show New CT Can Help Physicians Diagnose Heart Disease in Early Stages, pg 4.

Prevention of Out Migration

Scotland Memorial's residents choose to stay in Scotland County for their healthcare when possible. For its full time services, Scotland Memorial enjoys more than 70 percent average market share of Scotland County residents. This reflects both its positive reputation and, **more importantly**, the reliance and dependency the community has on Scotland Memorial to meet its healthcare needs.

Given the frequency of demand for cardiac procedures – of procedures performed on males in hospitals, one in four is a cardiac procedure;⁷ it is unreasonable to ask residents of Scotland Memorial Hospital's service area to travel an hour or more for this critical diagnostic procedure. For many, the time involved means a delay of hours or, more likely, days to get appropriate treatment. Time involved in stabilizing the patient, determining the diagnosis, arranging medical transport, coordinating care teams at the referral hospital adds up to critical time lost for the patient for whom timely cardiac catheterization is the best solution.

Scotland Memorial Hospital has mobile cardiac catheterization service available two days a week. The program has been well accepted by the community and referring physicians and the number of procedures has grown. However, with the service unavailable five days a week, many patients are referred elsewhere because time is critical to optimal care. Today, our physicians and emergency department refer more than ten percent of our cardiac catheterization patients to Pinehurst, UNC Chapel Hill, and Duke because of mobile service unavailability. However, many patients refuse to make that trip regardless of the exceptional quality available at these centers. For many patients, travel and cost are the ultimate barriers to care. Cardiac catheterization service needs to be available to Scotland Memorial patients on a full-time basis. A shared fixed laboratory would permit that.

Future Demand

Summary

Most Scotland County residents live 45 minutes to two hours away from the nearest cardiac catheterization equipment. The nearest providers are in Pinehurst and Lumberton, each approximately 45 minutes from Scotland Memorial Hospital; the Raleigh/Durham area providers are as much as two hours away. The cardiac service area for Scotland Memorial Hospital includes five counties: Scotland, Robeson, Hoke and Richmond Counties in North Carolina and Marlboro County in South Carolina and consists of approximately 289,000 people in 2007. The projected population of the service area is shown below.

⁷ Advance Data from Vital and Health Statistics No. 385, July 12, 2007, Center for Disease Control

Health Status

According to the NC State Center for Health Statistics, Scotland Memorial's North Carolina service area resident death rates are much higher than the State average. In 2005, heart disease represented 236 deaths per 100,000 Scotland County residents compared to the state's rate of 204.

Heart Disease Death Statistics

Geographical Area	Number of Deaths 2005	Death Rate 2005	Number of Deaths 2001-2005	Death Rate 2001-2005	Age-Adjusted Death Rate 2001-2005
Scotland	87	236.2	471	260.5	275.5
Robeson	285	223.2	1548	245.9	306.0
Richmond	137	293.5	836	358.7	338.7
Hoke	57	140.1	301	160.8	269.8
North Carolina	17,681	203.6	91,056	215.9	226.8
<i>Percent of State</i>					
Scotland		116%		121%	121%
Robeson		110%		114%	135%
Richmond		144%		166%	149%
Hoke		69%		74%	119%

Source: <http://www.schs.state.nc.us/SCHS/deaths/lcd/2005/heartdisease.html>

Data on South Carolina mortality rates indicate that heart disease is by far the leading cause of death among Marlboro County residents with a comparatively high rate of 409 deaths per 100,000 population.⁹

Cardiac Catheterization Utilization Rates

Cardiac catheterization, statewide, has experienced a steady increase for the past seven years. In 2006, there were 10.5 cardiac catheterizations per 1000 residents. The rate is trending towards 10.8 per 1,000 by 2009. Following this trend, Scotland Memorial Hospital needs only 15 percent market share of its service area to perform 500 cardiac catheterizations by 2010. In fact, our acute market share suggests that share would be even higher than 15 percent.

⁹ http://www.scdhec.gov/hs/epidata/reports/county_reports/mor/marlboro.pdf

No Unnecessary Duplication of Services

Scotland Memorial Hospital refers its cardiac care patients to Pinehurst, UNC and Duke. Pinehurst is 30 miles away and UNC and Duke are closer to 100 miles away for residents of Scotland's service area. FirstHealth performed nearly 3,500 cardiac catheterization and UNC and Duke together did more than 8,900. The additional number of cardiac catheterizations that will be done in Scotland County in lieu of FirstHealth, UNC or Duke will not be enough to make a difference in the viability of any of these programs. With better diagnostic capacity, Scotland's referrals to the specialty centers will likely increase. In fact, our mobile cardiac catheterization vendor and the hospital that receives most of our referrals for scheduling overflow and more specialized procedures, FirstHealth Moore Regional Hospital, is in full support of Scotland Memorial's petition. See Attachment C.

Alternatives

Status quo

With almost 3,000 residents of the Scotland Memorial Hospital service area needing cardiac catheterizations and 4,000 needing peripheral angiography, maintaining the status quo is not serving the population well.

Today, patients are treated in a space that is physically outside the hospital. Patients would avoid exposure to the elements in the trek between hospital and mobile unit, if we have a fixed unit. The service is not available every day; but patients get sick every day.

Status quo is not acceptable.

Mobile

Scotland Memorial Hospital will continue to offer mobile cardiac catheterization services as it has for more than fifteen years, but mobile service is only an interim solution. Though FirstHealth Moore Regional provides Scotland with quality equipment, mobile service is inefficient, adds overhead and is always at risk of a truck breakdown and / or damage to the equipment on the road. It can also compromise patient privacy with transport to and from the mobile unit.

Our successful mobile cardiac catheterization experience and demand for the service from our cardiologists and primary care physicians demonstrates our need and shows we can sustain the service.

Scotland Memorial has surpassed the threshold and added additional mobile time and will continue the less desirable mobile service. Ultimately, the only way for Scotland Memorial to sustain the threshold is holding down mobile days to force the fit, if necessary. If this proposal is not approved for inclusion in the 2008 State Medical Facilities Plan, the Scotland community will suffer through additional years of waiting to get the same advantage of a locally available cardiac catheterization service. A full-time cardiac catheterization service at Scotland Memorial will allow treatment of cardiac disease early with good results preventing the disease's progression to a later stage where patients require more drastic intervention.

Scotland Memorial has demonstrated success with the services it offers. Scotland has highly qualified, experienced physicians and staff in place to offer the service. Delaying Scotland Memorial patients' access to full-time cardiac catheterization service denies them access to quality cardiac care that could be provided successfully and cost effectively at home.

Conclusion

Scotland Memorial Hospital has the cardiologists, physicians and staff to support a full-time shared fixed cardiac catheterization service. It has demonstrated that it can sustain the volume of cardiac catheterizations needed to support the service. It has demonstrated that other area providers will not be adversely affected by the service. The service area has a high incidence of cardiac disease, and more than enough demand to support the service. Patients will benefit from the addition of a special need for a shared fixed cardiac catheterization laboratory in Scotland County in the 2008 State Medical Facilities Plan.

Attachments:

- A. Harvard Pilgrim HealthCare Technology Assessment Policy
- B. Centers for Medicare & Medicaid Article with excerpt from National Clearinghouse Guideline
- C. FirstHealth Moore Regional Support Letter
- D. Centers for Medicare & Medicaid Comment for Computer Tomographic Angiography

- *Technology Evaluation Center (TEC): Contrast-Enhanced Cardiac Computed Tomographic Angiography in the Diagnosis of Coronary Artery Stenosis or for Evaluation of Acute Chest Pain*, Volume 21, No. 5, August 2006.

The studies evaluating the use of CTA in comparison to angiography are relatively small studies from single centers. Their major failing is that they enrolled convenience samples of patients being referred for angiography. The results from these studies may not generalize to lower-risk populations. In addition, such studies only directly address the question of whether CTA can accurately triage patients already referred for angiography. The use of CTA as part of the initial workup of chest pain or possible angina is not addressed at all in these kinds of studies. Clinical trials comparing patients undergoing CTA as part of their diagnostic workup compared to patients not undergoing CTA may be required to demonstrate improved patient outcomes.

There is **no evidence** except in the ER regarding the use of CTA in the early workup of patients in whom CAD is being considered. Current published studies of CTA in the management of acute chest pain in the ER are clearly inadequate to determine utility. No comparator strategy was specified in any study, and there was no solid reference standard for diagnosis. Clinical trials may be necessary to demonstrate utility in this setting.

CTA as a substitute for coronary angiography in the diagnosis of coronary artery stenosis **does not meet the TEC criteria**. CTA in the evaluation of acute chest pain in the emergency room also does not meet the TEC criteria.

Based on Blue Cross Blue Shield Association national policy, computed tomographic angiography for coronary artery evaluation is considered **investigational**.

http://www.bcbs.com/tec/vol21/21_05.html

- *NLM, Medline, Cochrane Library, EMBASE, other:*

- Hoffmann MH, Shi H, Schmitz BL, Schmid FT, Lieberknecht M, Schulze R, Ludwig B, Kroschel U, Jahnke N, Haerer W, Brambs HJ, Aschoff AJ. *Noninvasive coronary angiography with multislice computed tomography*. JAMA. 2005 May 25;293(20):2471-8.

Hoffman et al had an objective to assess the accuracy and robustness of MSCT vs the criterion standard of invasive coronary angiography for detection of obstructive coronary artery disease. In a prospective, single center study conducted, 103 consecutive patients underwent both invasive coronary angiography and MSCT using a scanner with 16 detector rows. Blinded results for both modalities compared using the patient as the primary unit of analysis, with supplementary segment- and vessel-based analyses. One thousand three hundred eighty-four segments ($> \text{or } = 1.5 \text{ mm diameter}$) were identified by invasive coronary angiography; nondiagnostic image quality of MSCT was identified for only 88 (6.4%) of these segments, mainly due to faster heart rates. Compared with invasive coronary angiography for detection of significant lesions ($> 50\%$ stenosis), segment-based sensitivity, specificity, and positive and negative predictive values of MSCT were 95%, 98%, 87%, and 99%, respectively. Quantitative comparison of MSCT and invasive coronary angiography showed good correlation ($r = 0.87$, $P < .001$), with MSCT systematically measuring greater-percentage stenoses (bias, $+12\%$). Threshold optimization allowed either detection of these patients with 100% sensitivity at a reasonable false-positive rate (specificity, 76.5%; MSCT stenosis, $> 66\%$) or optimization of both the sensitivity and specificity ($> 90\%$; MSCT stenosis, $> 76\%$). The conclusion was that **Multislice computed tomography provides high accuracy** for noninvasive detection of suspected obstructive coronary artery disease. This promising technology has potential to **complement diagnostic invasive coronary angiography in routine clinical care**.

- Hacker M, Jakobs T, Matthiesen F, Vollmar C, Nikolaou K, Becker C, Knez A, Pfluger T, Reiser M, Hahn K, Tiling R. *Comparison of spiral multidetector CT angiography and myocardial perfusion imaging in the noninvasive detection of functionally relevant coronary artery lesions: first clinical experiences*. J Nucl Med. 2005 Aug;46(8):1294-300.

correlated well with IVUS. A **major limitation is the insufficient ability of CT to exactly quantify the degree of stenosis.**

- *American College of Radiology: (Oct 2005):*
In the ACR practice guideline for the performance and interpretation of CT angiography (CTA) suggests that CTA is a proven and useful procedure for the detection and characterization of vascular diseases and of vascular anatomy relevant to the treatment of extravascular disorders. CT angiography may be used as the primary modality for detecting disease or as an adjunctive tool for better characterizing known disease or assessing changes in disease state over time. While it is not possible to detect all abnormalities using CT angiography, adherence to the guidelines will maximize the probability of their detection.
- *Report of the American College of Cardiology Foundation: (2006)*
In the report, it suggests that Computed tomographic angiography, while very promising with regard to the detection of coronary stenoses, definition of "soft plaque," assessment of left ventricular function and congenital coronary anomalies, and evaluation of cardiac structures, has limited data supporting its use for many clinical applications, especially with regard to its role within patient care algorithms. In an effort to respond to the need for the rational use of these newer imaging techniques, cardiac computed tomography (CCT) and cardiac magnetic resonance (CMR) imaging, the American College of Cardiology Foundation, in conjunction with the societies listed on the report, undertook a process to determine the appropriateness of selected indications for the rapidly evolving cardiovascular imaging procedures. The Appropriateness Criteria Project was initiated to support the delivery of quality cardiovascular care and to ensure the effective use of diagnostic imaging tools.

2. Benchmarks:

- *Blue Cross Blue Shield of Mass.: (Jan 2006) Policy Updates mention "Clarified non-coverage for high-speed CT to include contrast-enhanced CT angiography for coronary artery evaluation performed with high-speed CT technology".*
http://www.bluecrossma.com/common/en_US/medical_policies/999.htm
- *BCBS (TEC): (Aug 2006) There is no evidence except in the ER regarding the use of CTA in the early workup of patients in whom CAD is being considered. Current published studies of CTA in the management of acute chest pain in the ER are clearly inadequate to determine utility. No comparator strategy was specified in any study, and there was no solid reference standard for diagnosis. Clinical trials may be necessary to demonstrate utility in this setting. CTA as a substitute for coronary angiography in the diagnosis of coronary artery stenosis **does not meet the TEC criteria.** CTA in the evaluation of acute chest pain in the emergency room also does not meet the TEC criteria.*
- *Aetna: (Jan 2006) Aetna considers cardiac CT angiography **experimental and investigational** for evaluating coronary artery disease, coronary artery bypass grafts, and coronary anomalies; it has not been proven to be as accurate as standard invasive coronary angiography for evaluating the coronary arteries.* <http://www.aetna.com/cpb/data/CPBA0228.html>
- *Tufts: No policy found*
- *Cigna: (Dec 2005) CIGNA HealthCare **does not cover** multidetector-row CTA for the following clinical indications because it is considered experimental, investigational or unproven:*
 - cardiac imaging, for coronary artery disease screening or diagnostic evaluation
 - screening in any asymptomatic populationhttp://www.cigna.com/health/provider/medical/procedural/coverage_positions/medical/mm_0399_coveragepositioncriteria_computed_tomography_angiography.pdf

6. A physician or qualified non-physician provider must be present during testing.
7. The electron beam tomography (EBT) technology is not covered.
8. The test may be denied on post-pay review as not being medically necessary when it is used for:
 - a) Coronary artery evaluation of a patient where there is pre-test knowledge of extensive coronary calcification that would diminish the interpretive value
 - b) Coronary artery evaluation of a patient presenting with an acute myocardial infarction or an acute coronary syndrome.
 - c) If performed prior to percutaneous revascularization in a patient who has already undergone diagnostic cardiac catheterization.
9. If PTCA follows Coronary CTA, diagnostic cardiac catheterization is considered not medically necessary.

Cost:

Applicable Codes:

HCPCS Codes

S 8093: Computed tomographic angiography, coronary arteries, with contrast material(s)

CPT Codes

- 0146T: Computed tomographic angiography of coronary arteries (including native and anomalous coronary arteries, coronary bypass grafts), without quantitative evaluation of coronary calcium
- 0147T: Computed tomographic angiography of coronary arteries (including native and anomalous coronary arteries, coronary bypass grafts), with quantitative evaluation of coronary calcium
- 0149T: Cardiac structure and morphology and computed tomographic angiography of coronary arteries (including native and anomalous coronary arteries, coronary bypass grafts), with quantitative evaluation of coronary calcium

References/Footnotes:

- 1) Hayes Medical Technology Directory. *Helical Computed Tomography for Coronary Artery Disease*, February 2000.
- 2) Hayes Technology Brief. *64-Slice Computed Tomography Angiography (CTA) for Coronary Artery Disease*. August 2005.
- 3) Blue Cross Blue Shield Association Technology Evaluation Center (TEC). *Electron Beam CT Scan, Ultrafast CT, Cine CT, & High-speed CT for heart disease and screening for lung cancer*. Policy 355, Reviewed Based on National Policy, 01/05
- 4) Blue Cross Blue Shield Association Technology Evaluation Center (TEC). *Contrast-Enhanced Cardiac Computed Tomographic Angiography in the Diagnosis of Coronary Artery Stenosis or for Evaluation of Acute Chest Pain*, Volume 21, No. 5, August 2006.
- 5) CMS, Medicare Coverage database.
http://www.cms.hhs.gov/mcd/viewmcd.asp?mcd_id=220.1&mcd_version=1&basket=mcd%3A220%2F1%3A1%3AComputerized+Tomography
- 6) CMS, National Heritage Insurance Company. LCD for Multislice or Multidetector Computed Tomographic Angiography of the Heart and Great vessels. March 2006.
http://www.medicarehnc.com/ne_prov/lmnp/draft/madraft_multicta1205.htm
- 7) Food and Drug Administration (FDA) [website]. Center for Devices and Radiological Health (CDRH). 510K database searched with JAK product code.
<http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMN/pmn.cfm>
- 8) ACR practice guideline for the performance and interpretation of CT angiography (CTA) October 2005. http://www.acr.org/s_acr/bin.asp?CID=546&DID=22486&DOC=FILE.PDF
- 9) American Society of Nuclear Cardiology. Computed Tomographic Imaging within Nuclear Cardiology Information Statement. November 2004.
http://www.asnc.org/yourpractice/computed_tomographic_imaging.pdf

Technology Assessments for Cardiac Catheterization Performed In Other Than A Hospital Setting (CAG-00166N)

Cardiac Catheterization in Freestanding Clinics

Issue

The Centers for Medicare and Medicaid Services (CMS) has discovered a discrepancy in section 35-45 of the Coverage Issues Manual (CIM). The policy states that cardiac catheterization may be covered in a freestanding clinic when the carrier, in consultation with the appropriate Peer Review Organization, determines that the procedure can be performed safely in all respects in the particular facility. The Peer Review Organizations (recently renamed Quality Improvement Organizations) ceased doing reviews of core freestanding, cardiac catheterization facilities in the early 1990s. Since the implementation of CIM 35-45, we are unaware of any emerging evidence that there is a greater risk of adverse events at these freestanding clinics. Therefore, CMS is opening this policy to review the evidence and correct the discrepancy.

AHRQ downloaded July 7, 2007

National Clearinghouse Guideline for Acute MI

A. Early Conservative Versus Invasive Strategies

Class I

- I. An early invasive strategy in patients with UA/NSTEMI without serious comorbidity and who have any of the following high-risk indicators (Level of Evidence: A):
 - a. Recurrent angina/ischemia at rest or with low-level activities despite intensive anti-ischemic therapy
 - b. Elevated troponin T (TnT) or troponin I (TnI)
 - c. New or presumably new ST-segment depression

Charles T. Frock
Chief Executive Officer

July 31, 2007

State Health Coordinating Council, and
Medical Facilities Planning Section
Division of Facility Services
2714 Mail Service Center
Raleigh, North Carolina 27699-2714

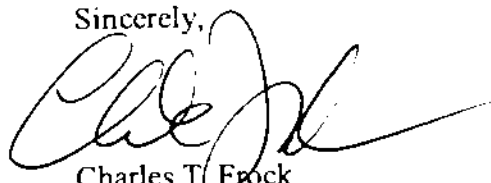
I am writing this letter to express support of Scotland Memorial Hospital's request for an adjustment in the need determination for Scotland County in the *Proposed 2008 State Medical Facilities Plan (SMFP)* to identify a need for one unit of shared fixed cardiac catheterization equipment in Scotland County.

As you are aware, we have been Scotland Memorial Hospital's mobile cardiac catheterization service provider since July 2002. We have been proud to work with the hospital and their cardiologists to help grow their volume from 62 procedures in 2001 to 427 procedures in 2006. The increase in cath procedures at Scotland Memorial Hospital has not negatively impacted our program. As a matter of fact, the hospital, our medical staff, and the patients have benefited greatly from a more coordinated working relationship between the two institutions.

Please accept this letter as our support of Scotland Memorial's request for an adjustment in the need determination in the *Proposed 2008 SMFP* for one unit of shared fixed cardiac catheterization equipment in Scotland County. If approved, we will work together to help establish a shared fixed cardiac catheterization service in Scotland County.

If you have any questions or require any additional information, please do not hesitate to contact me at 910-715-1442.

Sincerely,



Charles T. Frock
Chief Executive Officer

The CCTA Data Registry suggests that CCTA reduces cost to the healthcare system (Exhibit A). Substitutions for either catheter angiography or SPECT imaging generate savings. The findings from our registry suggest that the average cost, on a per patient basis for diagnostic imaging, was reduced by \$481 following the implementation of CCTA.

With 64-slice CCTA, a transition occurred within the cardiovascular diagnostic imaging arena. Both clinical performance and the number of applications were enhanced when combining 64-slice CCTA with several key components:

1. CCTA trained technologists
2. Detailed patient selection protocols
3. Efficacious scanning protocols
4. Highest concentration of contrast to allow visualization of smaller vessels
5. Physician leaders that meet or exceed the ACR/ACC competency statements
6. Key elements included uniformly within interpretations

Coronary Computed Tomography Angiography has emerged as an important non-invasive diagnostic technique for coronary disease as well as other cardiac problems. It is anticipated CCTA will dramatically alter the diagnostic paradigm for coronary artery disease.

EXHIBIT A:
Clinical and Economic Impact of CCTA: Preliminary Results of the CCTA Data Registry

A. Objectives

Using data from the CCTA Data Registry (Cardiovascular Innovations, LLC), we analyzed the impact of CCTA both clinically and economically.

B. Methods

64-slice CCTA data from 26 practices/hospitals (15,710 cases) across the United States participating in the CCTA Data Registry were reviewed for this analysis.

This economic analysis of the impact of CCTA services on reimbursements, along with a critical review of the clinical appropriateness and clinical impact of CCTA was conducted from November, 2005 through November, 2006. Data collection was performed in a similar manner at all institutions.

Data from every CCTA patient from each practice were included in the analysis. Data providing the clinical indications for CCTA, diagnostic imaging procedural volumes, global allowable reimbursement rates, normal catheterization rates, and patient volumes were obtained from the

of CCTA services, 15,710 CCTA procedures were added. Diagnostic catheter angiography volumes decreased (5%) in the twelve months following CCTA implementation despite an average 10% growth rate within the overall patient volumes in each practice. In addition, a marked reduction in nuclear perfusion studies ($n = 11,470$, 8%) occurred in the 12 month period following the introduction of CCTA into clinical practice. Despite the 10% overall patient growth rate during the measured time, nuclear perfusion volumes declined by 8% contradictory to what would have been predicted.

Normal Result Catheterization Rates

Normal Results Total Caths %

pre-CCTA 10,703 46,532 23%

post-CCTA 7,938 44,111 18%

A good barometer of the impact of a CCTA program is the percentage of patients having "normal" or "essentially normal" diagnostic catheter angiographies. A successful CCTA program should ideally reroute those moderate risk patients to the CCTA lab in lieu of traditional angiography, thereby reducing the number of normal results stemming from the diagnostic catheterization lab. Our results indicate a decline in normal results among catheterization patients. The observed 5% decline following CCTA implementation suggests that CCTA is being used appropriately, and that CCTA is adding clinical value to the overall diagnostic imaging program.

Clinical Indications for CCTA

Among states and payors that currently allow CCTA reimbursement, the most common clinical indications include; known coronary artery disease, prior revascularization, chest or precordial pain, shortness of breath, valve disorders, and angina. These indications allow the cardiovascular practitioner to non-invasively image the intermediate risk patient as well as monitor disease progression in the patient with known disease. Furthermore, these indications limit the scope of patients that are allowable for CCTA, thereby preventing the utilization of CCTA as a screening technique.

The clinical indications used by practitioners included in this analysis are presented below in a tabular format. Clinical Indication data from these practices for 2005-2006 clearly demonstrate that the physicians are employing appropriate clinical judgment when ordering CCTA studies. Furthermore, the clinical indication data suggest that these practices apply a very narrowly defined scope of indications for which CCTA is being ordered (96% of CCTA studies were ordered

Diagnostic Pathway 2: The patient proceeding from nuclear perfusion testing to CCTA will have had either an abnormal or equivocal nuclear study. Diagnostic Pathway 2 is a true substitution of CCTA for Cath. In the absence of a CCTA program the patient with an abnormal or equivocal nuclear study would instead progress to catheterization.

Multiply every Diagnostic Pathway 2 patient by the difference between the global allowable for a Cath (\$2800) and the \$1000 allowable for a CCTA.

Diagnostic Pathway 3: In Diagnostic Pathway 3, the symptomatic patient enters the diagnostic imaging pathway at CCTA as a substitution for a nuclear perfusion study. This pathway like Diagnostic Pathway 2 is a true substitution of imaging modalities with CCTA providing the less invasive and less expensive entry point.

Multiply every Diagnostic Pathway 3 patient by the difference between the global allowable for a nuclear perfusion study (\$1311) and the \$1000 allowable for a CCTA.

Diagnostic Pathway 4: The patients who enter the diagnostic imaging pathway with CCTA and then progress to a nuclear perfusion study comprise Diagnostic Pathway 4. A fraction of patients with an abnormal CCTA will require a perfusion study to evaluate the hemodynamic impact of the lesion(s). This pathway does not add or subtract a test, as this is a clinically appropriate pathway. In the absence of a CCTA program the practitioner would start at nuclear perfusion and potentially find a functional deficit that requires cath for anatomic evaluation.

Diagnostic Pathway 5: These patients first undergo a diagnostic catheter angiography and then progress to CCTA. This could occur for a variety of reasons, but the substitution is a CCTA for a nuclear perfusion study. In these instances the physician did not obtain the data needed from diagnostic catheterization alone and in the absence of a CCTA program a nuclear perfusion study would have been ordered.

Multiply every Diagnostic Pathway 5 patient by the difference between the global allowable for a nuclear perfusion study (\$1311) and the \$1000 allowable for a CCTA.

Layered Tests: These patients have all three diagnostic tests, which may occur for a variety of reasons. Since this pathway includes all 3 imaging modalities, and this is a major concern of the payors, we will multiply the number of patients on this pathway by the mean global reimbursement for CCTA (\$1000).

The Diagnostic Pathways utilized at these practices among the 15,710 CCTA patients are displayed below in tabular form.

and that CCTA adds clinical value to patient management while affecting a cost savings for the health care system. This conclusion is supported by the narrowly defined and appropriate clinical indications followed by these practices which are supported by the established Clinical Appropriateness Criteria. A decline in diagnostic procedural volumes for stress perfusion imaging and diagnostic catheter angiography following implementation of CCTA further supports this observation.

The economic analysis in this study predicts significant savings to the health care system following the implementation of a CCTA program. Despite the increase in the number of patients served at the institutions involved in this analysis, a decline in nuclear perfusion studies and invasive angiographic procedures occurred. The reduction among these procedures resulted in savings to the healthcare system of over seven million dollars within this cohort of patients. The savings on a per patient basis for diagnostic imaging was \$481. Directing patient evaluation to CCTA provides a safer, less invasive, more cost effective and potentially more accurate strategy for diagnosis of coronary disease.

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**Technology and Equipment
Committee Meeting**

August 29, 2007

CARDIAC CATHETERIZATION MATERIAL

Material Related to

Comments: Scotland Memorial

**Supplemental Information for Petitions filed by Halifax Regional Medical Center
and Scotland Memorial Hospital for Special Need Determination for Shared Fixed
Cardiac Catheterization Laboratories in Halifax and Scotland Counties.**

Petitioner 1:

Halifax Regional Medical Center
250 Smith Church Road
Roanoke Rapids, NC 27870

Petitioner 2:

Scotland Memorial Hospital
500 Lauchwood Drive
Laurinburg, NC 28352

Contact 1:

William Mahone, V
President
Halifax Regional Medical Center
250 Smith Church Road
Roanoke Rapids, NC 27870
(252) 535-8011

Contact 2:

Gregory C. Wood
President and CEO
Scotland Memorial Hospital
500 Lauchwood Drive
Laurinburg, NC 28352
Ph: 910-291-7501

The following information provided by Phillips shows the contents of a "cardiac package" that can be acquired and installed on an angiography laboratory to render it capable of producing high quality cardiac catheterization. Note that the angiography laboratory camera is designed with a wide field needed to view a peripheral vascular bed. The cardiac package provides hardware and software to narrow the camera aperture and increase the shutter speed to handle the requirements of a beating heart. The estimated cost of a package like this is approximately \$200,000. Thus, the adaptation costs of a shared lab make this a highly cost effective solution for a rural area.

By contrast, typically a cardiac catheterization laboratory has only the narrow aperture camera. The current MedCath laboratories are narrow aperture labs.

- | | | | |
|----------|------------------|----------------------------------|----------|
| 1 | **NNAE085 | Allura Xper FD20 Card Sys | 1 |
|----------|------------------|----------------------------------|----------|
- The Allura Xper FD20 Cardiac single plane cardiovascular system is comprised of a ceiling mounted stand and digital imaging X-ray system for cardiovascular diagnostic and interventional procedures
- The Allura Xper FD20 system uses an integrated single-host concept. The system is comprised of five functional building blocks: Geometry, X-ray Generation, User Interface, Image Detection, and Viewing. Each functional building block is explained in further detail.

Xres Cardiac (NCVA664)

- Xres Cardiac enhances sharpness, contrast, and reduces noise in fluoroscopy and exposure runs for cardiac studies

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PLANNING SECTION

13	**NCVA675	3D Roadmapping	1	\$52,260.00	\$52,260.00
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This extends the capabilities of the integrated 3D product by providing a sustainable 3D roadmap to support interventional procedures.

The 3D Roadmap option matches the real-time 2D fluoro images with the 3D reconstruction of the vessel tree. So one can see the advancement of the guide wire, catheter and coils on the 3D volume in real time

The 3D roadmap will remain if one changes the C-arm position, the SID and/or the Field of View of the flat detector. The 3D volume will follow automatically the orientation of the C-arc, providing the flexibility to chose the optimal position of the C-arc.



Greensboro PH
7-20-07
Cardiac Cath
Tom

**Comments on Proposed 2008 State Medical Facilities Plan
Greensboro, July 20, 2007**

Petitioner:

Scotland Memorial Hospital
500 Lauchwood Drive
Laurinburg, NC 28352
Ph: 910-291-7000

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JUL 20 2007

Medical Facilities
Planning Section

Contact:

Gregory C. Wood, President and CEO
Scotland Memorial Hospital
500 Lauchwood Drive
Laurinburg, NC 28352
Ph: 910-291-7000

Good afternoon, my name is Ruth Glaser. I have served as Vice President of Operations at Scotland Memorial Hospital and been a Scotland County community member since 1997. I am here today to comment on the proposed Methodology and Need Determination for Cardiac Catheterization Equipment in Scotland County. I am specifically here to request that the Plan be amended to include a shared fixed cardiac catheterization laboratory for Scotland County.

Let me first thank the State Health Coordinating Council (SHCC) and the Division of Facilities Services Planning Staff for providing the opportunity today for me to come and comment on the *Proposed 2008 State Medical Facilities Plan*.

Scotland Memorial Hospital is a 97-bed acute care facility in Laurinburg, North Carolina and has recently received State approval for 21 additional beds. We are independent, not for profit, and community owned. As the only hospital in rural Scotland County, Scotland

Memorial is the county's primary provider of inpatient acute care, diagnostic and therapeutic services, and emergency services. Laurinburg and Scotland Memorial Hospital are located on the Southern border of North Carolina and are surrounded by the rural counties of Scotland, Robeson, Richmond and Hoke in North Carolina and Marlboro County, South Carolina. These counties form Scotland Memorial's service area. Heart disease age-adjusted mortality rates in Scotland County are 121 percent of the State average, the percent of its population living below poverty is nearly 50 percent more than the State's and Scotland County's median income is only 74 percent of the State's median income. Averages in the other service area counties mirror Scotland's.

Our service area is rural. While urban residents become accustomed to driving on interstates and beltlines in congested traffic areas, this is not true for elderly people in rural areas. We have patients with third party coverage who refuse to leave Scotland County to get cardiac catheterization recommended by their physicians. Cost of travel is a barrier, access to transportation is a barrier, and access to a driver with time to transport is a barrier.

The State Plan's methodology for calculating need for a unit of shared fixed cardiac catheterization equipment itself is imperfect. The methodology sets a moving target based on the number of 8-hour days of mobile service. With one day of service a week, the target is 240 procedures. We have contracted for mobile cardiac catheterization service for more than fifteen years. As our utilization increases, nearing the 240-procedure threshold, scheduling procedures becomes difficult and our patients and physicians push to increase the number of days of mobile service. When we add an 8-hour day, or add an hour to a day, the target moves up 240 procedures a year for each eight hours a week. Scotland Memorial, in fact, surpassed the 240-procedure threshold in 2003, and was forced to add another day to provide adequate scheduling and good patient care. We ask that you give us a chance to make efficient use of our resources and technology to give residents of our service area access to the care that their insurance will cover.

As we considered the impact of waiting until the Plan shows a need in Scotland County, we realized the delay was not acceptable. Even with a need listed in the 2008 Plan, it will be 2010 before we would get a Certificate of Need approved. We are dealing with a population with advanced cardiac disease that needs adequate access to these services now. Please do not delay our ability to make this resource available 24/7 by yet another year. Our quality systems are in place, our staff is trained, we simply need access to the technology. We currently have 67 active physicians on our medical staff in a wide range of 20 specialties. We have two full-time and one part-time board certified cardiologists. We have experience providing this service with quality outcomes. We also have the appropriate physicians on staff with the required back up in place. Our cardiologists have performed over 1700 cardiac catheterization procedures at Scotland Memorial since 2002. Yet, we are forced to refer out many service area patients to First Health Moore, UNC and Duke each year because mobile cardiac cath service limits our capacity so severely. Making us wait only increases the overhead we pay to a mobile provider and restricts the availability of the service.

Anyone who has worked with a mobile service knows the drawbacks. Trucks break down, equipment is jostled, patient privacy is compromised, and most importantly, the equipment is not there when the patients most need it.

With over 3,000 cardiac catheterizations in our service area every year, it will take only a token 7 percent market share to surpass the 225 procedure threshold required by Administrative Rule 10A NCAC 14C .1603 (d) Performance Standards for shared fixed cardiac cath equipment. A conservative market share of 15 percent will sustain a strong shared fixed cardiac catheterization laboratory with more than double the 225 shared procedure threshold. More importantly, offering a shared fixed lab will permit our medical staff to give our patients the healthcare services they deserve in their home community.

I understand the role of the State Planning process in containing costs and minimizing duplication. It is equally important to consider the second basic plan principle, -

improving access. North Carolina's urban centers: Charlotte, Asheville and Raleigh are growing rapidly and have many more medical resources. We can do a better job of sustained growth in North Carolina if we think about spreading the resources in a way that makes the outlying communities attractive. To support our residents, we need the technology to make our medical support system attractive to physicians, nurses and health-care technologists. Cardiac catheterization rates have been steadily increasing in North Carolina, about 2 percent a year for the past seven years. Permitting us to do a limited number of procedures at Scotland Memorial Hospital will not hurt any of the existing programs. Increases in use rate and population will more than offset any procedures that might remain in Scotland County rather than travel outside.

Failing to request an adjustment in the need determination for Scotland County to include a shared fixed cath lab would be failing to continue our mission of providing our community with high quality, compassionate health care. With only two days of mobile cardiac cath services, we are already compromising the service patients and their family member's desire and deserve -- any growth in use rate or population will make it worse.

It is with that goal in mind that we are petitioning the Medical Facilities Planning Section to adjust the need determination in the Proposed 2008 SMFP to identify a need for one shared fixed cardiac catheterization laboratory in Scotland County. We believe based on historical utilization, statistical analysis, physician recruitment, physical space and staffing patterns at Scotland Memorial Hospital that adding a shared fixed lab is the most efficient way to meet the hospital's and our service area's need for cardiac care. The formal petition we will submit includes the data and the analyses used to arrive at this decision.

Our request is made to serve our community appropriately. It is not about expanding our territory, nor are we expanding our competitive efforts. I do not expect other hospitals in our adjoining counties to dispute our request nor are we duplicating their services. In fact, our mobile service provider and the hospital that receives most of the referrals for caths we cannot do, FirstHealth Moore Regional Hospital, is in full support of our

petition. No other viable alternative exists that would not create continued adverse effects on our county's residents.

In conclusion and on behalf of Scotland Memorial Hospital, I first want to thank the SHCC and Planning Staff for their service to our state. This process is still the soundest mechanism for fairly determining health care-needs for our great state.

On behalf of our Board, staff, and physicians and more importantly, our service area residents and Scotland Memorial Hospital patients, I want to thank you for the opportunity to make this request today. Failing to grant our request would be unfair to Scotland Memorial service area residents and would fail to promote adequate access to quality health care services for those residents.

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Petition\PublicHearingComments_Greensboro.doc

Raleigh PH
8-1-07
Cardiac Cath

Comments on Proposed 2008 State Medical Facilities Plan
Raleigh, August 1, 2007

Petitioner:

Scotland Memorial Hospital
500 Lauchwood Drive
Laurinburg, NC 28352
Ph: 910-291-7000

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MEDICAL FACILITIES
PLANNING SECTION

Contact:

Gregory C. Wood, President and CEO
Scotland Memorial Hospital
500 Lauchwood Drive
Laurinburg, NC 28352
Ph: 910-291-7000

Good afternoon, my name is Greg Wood. I have served as the President and Chief Executive Officer of Scotland Memorial Hospital and been a Scotland County community member since 1990. I am here today to comment on the proposed Methodology and Need Determination for Cardiac Catheterization Equipment in Scotland County. I am specifically here to request that the Plan be amended to include a shared fixed cardiac catheterization laboratory for Scotland County.

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Scotland Memorial Hospital is a 97-bed acute care facility in Laurinburg, North Carolina and has recently received State approval for 21 additional beds. We are independent, not for profit, and community owned. As the only hospital in rural Scotland County, Scotland

to the mobile pad outside the front entrance of the hospital. When the procedure is complete, they are wheeled back through the hallways to recovery.

Continuing to add mobile days of cardiac cath service and waiting until the Plan shows a need in Scotland County will result in an unacceptably long delay in full-time cardiac cath service in Scotland County. Even with a need listed in the 2008 Plan, it will be 2010 before we could begin servicing our community. We are dealing with a population with advanced cardiac disease that needs adequate access to these services now. Please do not delay our ability to make this resource available 24/7 by yet another year. We currently have 67 active physicians on our medical staff in a wide range of 20 specialties. We have two full-time and one part-time board certified cardiologists, with a verbal offer recently extended to a locally born cardiologist finishing his fellowship. We have experience providing this service with quality outcomes. We also have the appropriate physicians on staff with the required back up in place. Our cardiologists have performed over 1,700 caths at Scotland Memorial since 2002 -- more than enough to remain proficient. Yet, we are forced to refer out many service area patients to First Health Moore, UNC and Duke each year because mobile cardiac cath service limits our capacity so severely and we do not have a 64-slice C.T. Making us wait only increases the overhead we pay to a mobile provider and restricts the availability of the service.

With over 3,000 cardiac catheterizations in our service area every year, it will take only a token 7 percent market share to surpass the 225 procedure threshold required by Administrative Rule 10A NCAC 14C .1603 (d) Performance Standards for shared fixed cardiac cath equipment. A conservative market share of 15 percent will sustain a strong shared fixed cardiac catheterization laboratory with more than double the 225 shared procedure threshold. More importantly, offering a shared fixed lab will permit our medical staff to give our patients the healthcare services they deserve in their home community.

The role of the State Planning process in containing costs and minimizing duplication is an important one. It is equally important to consider the second basic plan principal, -

viable alternative exists that would not create continued adverse effects on our county's residents.

In conclusion, I want to thank the SHCC and Planning Staff for their service to our state. This process is still the soundest mechanism for fairly determining health care needs for our great state.

And, on behalf of our Board, staff, and physicians and more importantly, our service area residents and Scotland Memorial Hospital patients, I want to thank you for the opportunity to make this request today. Failing to grant our request would fail to promote adequate access to quality health care services for those residents.

Thank you.